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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/440,829	11/15/1999	ALEX CHENCHIK	CLON-015	3481

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EXAMINER

FORMAN, BETTY J

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 08/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

84.

## Office Action Summary

**Application No.**

09/440,829

**Applicant(s)**

CHENCHIK ET AL.

**Examiner**

BJ Forman

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3,8,10-23 and 35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,8,10-23 and 35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 7/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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## **FINAL ACTION**

### ***Status of the Claims***

1. This action is in response to papers filed 29 June 2004 in which the specification and claims 1, 8, 10, 11, 14, 19, 20 and 23 were amended and claims 7 and 9 were canceled and further in response to a Supplemental Information Disclosure Statement filed 16 July 2004. All of the amendments have been thoroughly reviewed and entered.

The previous objections and rejections in the Office Action dated 30 March 2004 are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection, necessitated by the Information Disclosure Statement, are discussed.

Claims 1-3, 8, 10-23 and 35 are under prosecution.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-3, 8, 10-23 are rejected under 35 U.S.C. 102(e) as anticipated by Church et al (U.S. Patent No. 6,548,021, filed 11 August 1998).

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Regarding Claim 1, Church et al disclose an array comprising a pattern of probe spots covalently attached to the surface of a solid support (Column 14, lines 42-44) wherein the spots on the array have a density of at least  $10/\text{cm}^2$  (Column 3, lines 31-33) and each spot comprises an oligonucleotide probe composition made up of long probes having a length of 60 to about 100nt (Column 8, lines 31-35 and Column 13, line 65-Column 14, line 45).

The instant claims are drawn to probe having a length ranging from 60 to 100nt. Church et al teach probes of 60nt. Because Church et al teach probes within the claimed range length, they anticipate the claimed probes.

Furthermore, Church teach the probes are covalently attached to the support via a spacer comprising a surface attaching portion and a longer chain portion (Column 3, lines 49-53) wherein the longer chain portion is a polynucleotide (Column 15, lines 3-10). Hence, the probes of Church are 60nt plus the additional polynucleotide spacer. Therefore, the probes are encompassed by the claimed range of 60 to about 100nt.

Regarding Claim 2, Church et al disclose the array wherein two or more nucleic acids hybridize to different probes (Abstract and Column 3, lines 8-13). Church et al teach each probe-primer hybrid forms a different recognition site. Examples of recognition site sequences are listed at Column 12-13. Because the different recognition sites differ in sequence, probes of the array hybridize to different targets i.e. primers.

Regarding Claim 3, Church et al disclose the array wherein each probe is hybridizes to a different target (Column 3, lines 8-13 and 30-32).

Regarding Claim 8, Church et al disclose the array wherein the probes are cross-linked to the surface (Column 14, lines 44-64).

Regarding Claim 10, Church et al disclose the array wherein the spots do not exceed a density of  $1000/\text{cm}^2$  (Column 3, lines 31-33).

Regarding Claim 11, Church et al disclose the array wherein the spots do not exceed a density of  $400/\text{cm}^2$  (Column 3, lines 31-33).

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Regarding Claim 12, Church et al disclose the array wherein the spots range in number from about 50 to 5,000 (Column 3, lines 31-34).

Regarding Claim 14, Church et al disclose an array comprising a pattern of probe spots covalently bound to the surface of a solid support (Column 14, lines 42-44) wherein the spots on the array have a density of at least  $10/\text{cm}^2$  (Column 3, lines 31-33) and each spot comprises an oligonucleotide probe composition made up of long probes having a length of 60nt bound to the surface of the support (Column 8, lines 31-35 and Column 13, line 65-Column 14, line 45).

Regarding Claim 15, Church et al disclose the array comprises ten or more different probe spots which hybridize to different targets (Column 3, lines 30-32).

Regarding Claim 16, Church et al disclose the array wherein each probe hybridizes to a different target (Column 3, lines 8-13 and 30-32).

Regarding Claim 17, Church et al disclose the array wherein two or more nucleic acids hybridize to different probes (Abstract and Column 3, lines 8-13). Church et al teach each probe-primer hybrid forms a different recognition site. Examples of recognition site sequences are listed at Column 12-13. Because the different recognition sites differ in sequence, probes of the array hybridize to different targets i.e. primers.

Regarding Claim 18, Church et al disclose the array wherein the probes are about 65nt i.e. 60nt plus spacer (Column 8, lines 31-35 and Column 13, line 65-Column 14, line 45).

Church teach the probes are covalently attached to the support via a spacer comprising a surface attaching portion and a longer chain portion (Column 3, lines 49-53) wherein the longer chain portion is a polynucleotide (Column 15, lines 3-10). Hence, the probes of Church are 60nt plus the additional polynucleotide spacer. Therefore, the probes are encompassed by the claimed range of 65 to about 95nt.

Regarding Claim 19, Church et al disclose the array wherein the spots do not exceed a density of  $1000/\text{cm}^2$  (Column 3, lines 31-33).

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Regarding Claim 20, Church et al disclose the array wherein the spots do not exceed a density of 400/cm<sup>2</sup> (Column 3, lines 31-33).

Regarding Claim 21, Church et al disclose the array wherein the spots range in number from about 50 to 5,000 (Column 3, lines 31-34).

Regarding Claim 22, Church et al disclose the array wherein the spots range in number from about 50 to 5,000 (Column 3, lines 31-33).

Regarding Claim 23, Church et al disclose an array comprising a pattern of probe spots at a density of at least 10/cm<sup>2</sup> and does not exceed a density of 400/cm<sup>2</sup> (Column 3, lines 31-33) wherein and each spot comprises an oligonucleotide probe composition made up of long probes having a length of about 65 to 90nt covalently bound to the surface of the support (Column 8, lines 31-35 and Column 13, line 65-Column 14, line 45).

Church teach the probes are covalently attached to the support via a spacer comprising a surface attaching portion and a longer chain portion (Column 3, lines 49-53) wherein the longer chain portion is a polynucleotide (Column 15, lines 3-10). Hence, the probes of Church are 60nt plus the additional polynucleotide spacer. Therefore, the probes are encompassed by the claimed range of about 65 to about 95nt.

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Church et al (U.S. Patent No. 6,548,021, filed 11 August 1998) in view of Stratagene Catalog (1988, page 39).

Regarding Claim 35, Church et al disclose the array of Claim 1 comprising a pattern of probe spots covalently attached to the surface of a solid support (Column 14, lines 42-44) wherein the spots on the array have a density of at least 10/cm<sup>2</sup> (Column 3, lines 31-33) and each spot comprises an oligonucleotide probe composition made up of long probes having a length of 60 to about 100nt (Column 8, lines 31-35 and Column 13, line 65-Column 14, line 45) but they do not teach the array combined into a kit format.

However, Stratagene catalog teaches a motivation to combine reagents into kit format (page 39). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the array of Church et al into a kit format as discussed by Stratagene catalog since the Stratagene catalog teaches a motivation for combining reagents of use in an assay into a kit, "Each kit provides two services: 1) a variety of different reagents have been assembled and pre-mixed specifically for a desired set of experiments. 2) The other service provided in a kit is quality control" (page 39, column 1).

6. Applicant's Information Disclosure Statement necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

### **Conclusion**

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.



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BJ Forman, Ph.D.  
Primary Examiner  
Art Unit: 1634  
August 3, 2004